K080674

510(k) Premarket Notification Submission: MAY - 9 2008

Summary of Safety and Effectiveness

Date of Preparation: March 6th 2008

Submitter Information/ production site:

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Establishment Registration Number: **9611612**

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Contract Sterilizer:
STERIGENICS GERMANY GMBH
Rheingaustrasse 190-196
65203 Wiesbaden, GERMANY
Registration Number: 3002807090
Operations: Contract Sterilizer
Status: Active

Device Information:

Device Name:	**PAJUNK®'s PrimoCut Disposable Biopsy system**
Trade Names:	**PrimoCut**
Common Name:	**Biopsy cannula, Instrument/ Needle, Kit, Biopsy**
Classification Name:	**Gastroenterology-urology biopsy instrument**
Classification Reference:	**21 CFR §876.1075, April 1, 2007**
Establishment Registration Number:	**9611612**
Regulatory Class:	**II**
Product Code:	**KNW**
Panel:	**Gastroenterology/Urology**
Predicate Devices:	1. **K052802** Manan BioCut soft tissue Biopsy needle 2. **K024120 TEMNO® semi automated biopsy device, Allegiance**

Indications for use:

PAJUNK®'s PrimoCut Disposable Biopsy system is indicated for soft tissue biopsy.

Device Description:

With PrimoCut, PAJUNK® has developed a disposable cannula system which was especially designed for the extraction of biopsies from soft tissue and soft tissue tumors. Depending on the size of the biopsy material desired, there are two different dissecting lengths to choose from: 6 mm, or 15 mm. Different from the multiple-use biopsy system DeltaCut, the activating mechanism of the PrimoCut is directly integrated in the connecting hub of the cannula. This more economical alternative is disposed of completely after use.

Predicate Devices:

Predicate devices with identical indications of use are:

3. K052802 Manan BioCut soft tissue Biopsy needle
4. K024120 TEMNO® semi automated biopsy device, Allegiance

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

Sterilization

The device is single use, sterilized with EtO. The contract sterilizer and the sterilizing process is the same as that used for all Pajunk Products already cleared for market.

Technology Characteristics:

The PrimoCut is a semi-automated, spring loaded, sterile disposable device for soft tissue biopsies.

Conclusion:

The comparison between the predicate devices and the subject device in section 12 of this submission as well as the validated sterilization process and the results of the bench testing and bench marking demonstrates that the proposed devices are substantially equivalent to the predicate devices and identical in technical description to devices already cleared for market and therefore demonstrated to be safe and effective. Based on the clinical evaluation, the biocompatibility testing and the bench testing conducted the efficacy of PAJUNK®'s **PrimoCut** is proven.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH Medizintechnologie
% Christian Quass
Director, Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

MAY - 9 2008

Re: K080674
Trade/Device Name: PAJUNK®'s PrimoCut Disposable Biopsy System
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: MJG
Dated: April 21, 2008
Received: April 23, 2008

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: K080674

Device Name: PAJUNK®'s PrimoCut Disposable Biopsy system

Indications for Use:

PAJUNK®'s PrimoCut Disposable Biopsy system is indicated for soft tissue biopsy.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mcn

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K080674